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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,822	04/13/2001	Peter David Gill	7500.360US01	4302
23552	7590	04/29/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			TUNG, JOYCE	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

818

Office Action Summary

Application No.

09/834,822

Applicant(s)

GILL ET AL.

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 24-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/23/2001, 4/10/200
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The applicant's response filed 12/30/2003 to the Office action has been entered. Claims 1-40 are pending and claims 1-23 are examined as follows:

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-23 in Paper No. 12302003 are acknowledged. The traversal is on the ground(s) that the restriction requirement should be withdrawn because Group II, claims 24-40 are drawn to a method of indicating a likelihood ratio in which claim 24 is more explicit than the general claims 1 and 2. This is not found persuasive because Group II claims 24-40 have a different method step, for example, the determination of at least some of the theoretical allele identities that is not presented in Group I, claims 1-23.

Therefore, they are different inventions. Thus, the requirement is still deemed proper and is therefore made FINAL.

2. Claims 24-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II, claims 24-40, their being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12302003 as discussed in section 1.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 1-23 are vague and indefinite because the languages are prolix and are not comprehensive. It is unclear how the method is performed in terms of comparing one or more reference samples of DNA from known individuals
- b. Claims 1-23 are vague and indefinite because the language “spurious information” is unclear what is the definition of the term. Clarification is required.
- c. Claims 1-23 are vague and indefinite because of the language “contamination, stutter, allele dropout or artifact”. It is unclear how they are defined. Clarification is required.
- d. Claims 1-23 recite the limitation, for example, “the determination of the identity of the alleles” and “in the test sample” in claims 1 and 2, and “the consideration of one of the plurality of individual test results” in claim 1 and “ the determination defining an individual test result” in claims 1 and 2. There is insufficient antecedent basis for these limitations in the claims.
- f. Claims 1-23 are vague and indefinite because of the phrase “including” in claims 1 and 2. It is unclear what is the scope of the claims by using the phrase “including”. It is suggested to use the phrase “comprising” since the phrase “comprising” is also open language.
- g. Claims 1-23 are vague and indefinite because no active steps are recited which define the method of comparing one or more reference samples of DNA from known

individuals. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion. See Ex parte Erlich, 3 USPQ2d, p. 1011 (Bd. Pat. App. Int. 1986).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-9 and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Weir et al. (J. of Forensic Science, 1997, Vol. 42 (2), pg. 213-222).

Weir et al. disclose the interpretation of mixed DNA, which is explained in the context of likelihood ratios. The probabilities for the mixed stain profile are evaluated under the explanation that specify the numbers of contributors and the profiles of any known contributors (See pg. 213, the abstract and pg. 214, column 1). The alleles are identified by the probabilities (See pg. 214, column 2).

Since the claim languages are so confusing that the claimed method is not easy to understand, it appears that the only limitation is to determine the identity of the alleles present at a locus in a test sample by an expression of probability, the teachings of Weir et al. anticipate the limitations of the claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1637

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weir et al. (J. of Forensic Science, 1997, Vol. 42 (2), pg. 213-222) as applied to claims 1-9, and 21-23 above, and further in view of Duff et al. (6,713,253, issued March 20, 2004).

The teachings of Weir et al. are set forth in section 6 above. Weir et al. do not disclose using one or more control determinations to decide whether there is a contamination, or stutter or allele dropout or artifact occurred in probability function.

Duff et al. disclose a method of predicting increased risk of diabetic retinopathy (See the Abstract). The identified pattern is compared with control patterns of known polymorphisms (See the Abstract and column 5, lines 52-56). The different alleles present at each of the typed loci may be compared with control standards to allow identify of the alleles (See column 11, lines 46-51). The likelihood ratio is used to analyze combinations of cytokine gene polymorphisms (See column 12, lines 39-50).

Art Unit: 1637

Since the claims do not specifically define what is the contamination, stutter, allele dropout or artifact, one of the ordinary skill in the art would have been motivated to apply control pattern or control populations as control determinations to the method of Weir et al to determine the contamination, stutter, allele dropout or artifact in the probability because the method of Duff et al. involving the control pattern and control population is useful for identifying diabetic patients at risk for sight-threatening retinopathy to allow early treatment. It would have been prima facie obvious to apply one or more control determinations to decide whether there is the contamination, stutter, allele dropout or artifact which may occur in the probability function.

Summary

9. No claims are allowable.

Art Unit: 1637

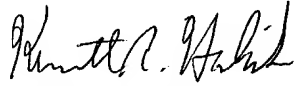
10. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung J.T
April 23, 2004


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
4/28/04